

NitroMed Stops Heart Failure Study (A-HeFT) in African Americans Due to Significant Survival Benefit of BiDil®

Company Makes BiDil Available to All Patients in Study

NitroMed Will Hold Conference Call Today, Monday, July 19 at 9:00 a.m. Eastern Time to Discuss A-HeFT

LEXINGTON, Mass. - (BUSINESS WIRE) - July 19, 2004 - NitroMed, Inc. (NASDAQ: NTMD) announced today it has halted the Phase III clinical trial of BiDil, its lead drug in development for the treatment of African Americans with heart failure. The trial was stopped because of the significant survival benefit seen with the drug. The action followed the unanimous recommendations of both the Data Safety and Monitoring Board (DSMB) and the Steering Committee for the trial.

The African American Heart Failure Trial, or A-HeFT, was designed to evaluate the efficacy of BiDil, when taken daily in addition to the best current therapy. BiDil is an orally administered nitric oxide enhancing medicine which combines isosorbide dinitrate and hydralazine. Over 1,000 patients in 170 sites across the United States were enrolled in the double blind placebo controlled trial. The Association of Black Cardiologists is a joint sponsor of the study.

Early this morning, the Company notified the study investigators at the 170 active clinical sites throughout the country that the trial is to be halted immediately. All patients in the A-HeFT trial will now have the opportunity to be treated with BiDil.

"The reported benefit of BiDil and the recommendation of the DSMB were so compelling that the A-HeFT Steering Committee unanimously recommended that the trial be stopped," said Dr. Anne Taylor, Chairman of the A-HeFT Steering Committee and Professor of Medicine, University of Minnesota School of Medicine. The DSMB is an independent committee of experts who oversees the trial to ensure patient safety. Based on the size and consistency of the survival benefit, the committee believed it would be unethical for physicians to continue to withhold BiDil from patients taking a placebo in the study.

Although the data reviewed were preliminary and will require more robust analysis, the statistically significant survival benefit was consistent with and confirmed by the A-HeFT primary composite endpoint of mortality, first hospitalization for heart failure and quality of life. The preliminary data also indicated that serious adverse events and cardiovascular events in particular, were less frequently observed in the BiDil arm of the trial. BiDil is not yet approved for marketing by the FDA. NitroMed expects that the data from the trial will be available in the fourth quarter of 2004.

Dr. Manuel Worcel, NitroMed's Chief Medical Officer, observed, "The survival benefit with BiDil in African American heart failure patients is consistent with the survival benefit observed in an earlier clinical study, V-HeFT I, where patients were given BiDil on top of then current therapies digoxin and diuretics. In the A-HeFT trial, patients were given BiDil in addition to the full spectrum of modern therapies which may include beta blockers, angiotensin antagonists and aldosterone inhibitors—as well as digoxin and diuretics."

"A-HeFT is the largest database ever in African-Americans with heart failure and highlights the importance of African American participation in clinical trials. The Association of Black Cardiologists is proud to be the co-sponsor of the trial," said Malcolm Taylor, M.D., Chair of the Association of Black Cardiologist Heart Failure Steering Committee and member of the A-HeFT Steering Committee.

Michael D. Loberg, Ph.D., President and C.E.O., NitroMed commented, "Today's news indeed accelerates our timetable and, I believe, lowers our development risk to commercialization. Although the data need further analysis, NitroMed will work closely with the FDA to conclude the necessary A-HeFT data analysis and to ensure a complete and prompt filing of the data as an amendment to our previously submitted new drug application (NDA). At the same time, we intend to have the necessary commercial resources in place to support a product launch by early 2005."

CONFERENCE CALL TODAY – INFORMATION

NitroMed will hold a conference call today, Monday, July 19 at 9:00 a.m. Eastern to discuss the A-HeFT trial and to answer questions. Participating in the call with NitroMed management will be Dr. Anne Taylor, Chairman of the A-HeFT Steering Committee and Dr. Clyde Yancy who is a member of the Steering Committee.

The conference may be heard live via the investor relations section of our website at www.nitromed.com. The call can also be accessed by telephone by dialing 800-299-0433. The participant pass code is 89324651.

Replay of the broadcast will be available on the website and by calling 888-286-8010 and using pass code 27882245.

A-HeFT First Heart Failure Trial in African Americans

A-HeFT is the first and only heart failure trial conducted in an all African American patient population, testing the effects of BiDil, when administered in addition to current heart failure therapy. The trial was expected to be completed in early 2005.

African Americans and Heart Failure

Heart failure—or end-stage cardiovascular disease—affects approximately five million Americans. There is no cure for this disease and more than 50% of patients die within five years of diagnosis. African Americans suffer a disproportionate incidence of cardiovascular disease. With respect to heart failure, they are affected at a rate greater than that of the corresponding white population and are more likely to die from it. They also present with the disease at a much younger age. This dramatic ethnic difference in health outcomes has been attributed to a variety of factors, including access to medical care, management of heart failure and socioeconomic factors.

Recent analyses of heart failure clinical trials, however, show that the mortality rate and the hospitalization rate for African Americans is significantly higher than for non-African Americans, even after adjustment for such factors. Based on data from the Census Bureau and the Centers for Disease Control, it is estimated that annually there are 750,000 African Americans with heart failure in the United States, and this number is expected to grow to approximately 900,000 persons by 2010.

About BiDil®

As the lead product in development for NitroMed, BiDil is an orally-administered nitric oxide-enhancing medicine that is being investigated for its potential to reduce mortality and hospitalization and improve the quality of life of African Americans diagnosed with heart failure. BiDil is a combination of two drugs, isosorbide dinitrate and hydralazine. Isosorbide dinitrate is a nitric oxide donor. Hydralazine is an antioxidant and vasodilator agent, which means that it dilates blood vessels and protects the nitric oxide formed by isosorbide dinitrate from deactivating.

Neither drug separately is indicated for heart failure. Because heart failure is a chronic disease, if approved, BiDil, like other medicines taken for chronic heart disease, will be taken for the duration of the patient's life.

The Design of A-HeFT

A-HeFT was designed to demonstrate that BiDil, when administered together with standard heart failure therapies, can provide a combination of reduced mortality and hospitalization for heart failure and improved quality of life for African Americans with heart failure. The trial was designed as a randomized, double blind, placebo controlled study targeted to enroll 1,100 black men and women with moderate to severe heart failure, categorized as New York Heart Association (NYHA) heart failure functional classifications III and IV. Eligible patients were also required to have a reduced ability of the heart to pump blood efficiently, as characterized by a decreased ejection fraction as well as enlarged left ventricles. Patients were enrolled in the study at 170 clinical sites throughout the United States.

The study treatment included either BiDil or a placebo in addition to the patient's standard course of treatment for their heart failure, which may have included angiotensin converting enzyme (ACE)-inhibitors, angiotensin receptor blockers, beta-blockers, diuretics, spironolactone and digitalis.

About NitroMed, Inc.

NitroMed is an emerging pharmaceutical company that discovers, develops and seeks to commercialize proprietary pharmaceuticals based on the therapeutic benefits of the naturally occurring molecule nitric oxide. The Company uses its expertise in nitric oxide biology and chemistry in an effort to develop both novel drugs, as well as safer, more effective versions of existing drugs. Research and development efforts focus on major diseases that are characterized by a deficiency in nitric oxide, such as cardiovascular and inflammatory diseases.

Collaborative partnerships are a key element of the Company's business strategy. NitroMed has agreements with Merck to jointly develop nitric oxide-based COX-2 inhibitors and with Boston Scientific to jointly develop nitric oxide coated cardiovascular stents. Its lead COX-2 inhibitor being developed with Merck is in Phase II clinical trials.

Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements regarding the Company's timeline for seeking to obtain regulatory approval for BiDil®, and its expectations regarding development risk, as well as statements containing the words "believes," "anticipates," "plans," "expects," "will," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: difficulties or delays relating to obtaining required regulatory approvals to develop, market and sell BiDil; the Company's ability to successfully complete clinical trial data analysis of BiDil; the Company's dependence on corporate collaborators to develop, manufacture, market and sell products based upon its technologies; the Company's failure to obtain or maintain intellectual property protection and required licenses for its technologies and products under development; the Company's ability to obtain the substantial additional funding required to conduct research and development, manufacturing, marketing and sales of its products under development; and other factors discussed in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2004 and other filings that it periodically makes with the SEC. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this release.

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